**S. AMANDA MARSHALL**, OSB # 95347
United States Attorney
**NEIL J. EVANS**, OSB # 965515
neil.evans@usdoj.gov
United States Attorney's Office
District of Oregon
1000 SW Third Avenue, Suite 600
Portland, Oregon 97204-2902
Telephone: (503) 727-1053
Facsimile: (503) 727-1117

**JOHN W. BURKE**
josh.burke@usdoj.gov
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
Civil Division
P.O. Box 386
Washington, DC 20044
(202) 353-2001



**IN THE UNITED STATES DISTRICT COURT**

**FOR THE DISTRICT OF OREGON**

**EUGENE DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

v.

TRUMAN J. BERST, an individual d/b/a ALTERNATIVE HEALTH & HERBS REMEDIES,

Defendant.

**Case No.:** 11-6370-TC

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Truman J. Berst, an individual, doing business as Alternative Health & Herbs Remedies, from violating:

a. 21 U.S.C. § 331(d), by introducing or delivering, and/or causing to be introduced or delivered, into interstate commerce any new drug within the meaning of 21 U.S.C. § 321(p) that is neither approved under 21 U.S.C. § 355(a) or (j), nor exempt from approval pursuant to 21 U.S.C. § 355(i); and

b. 21 U.S.C. § 331(a), by introducing or delivering, and/or causing to be introduced or delivered, into interstate commerce any article of drug that is misbranded within the meaning of 21 U.S.C. § 352(f)(1).

## JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b).

## DEFENDANT

4. Defendant Truman J. Berst is a sole proprietor doing business as Alternative Health & Herbs Remedies. Defendant operates his business from an office located at 37386 Soap Creek Road, Corvallis, Oregon 97330. He manufactures the

products promoted and distributed by his business at a facility located at 425 Jackson Street SE, Albany, Oregon 97321.

5. Defendant promotes and distributes numerous products, including single herbal tinctures, tincture formulations, capsules, topical products, and eyewash products. Among the products Defendant promotes and distributes are Eyebright Leaf (Euphrasia officinalis) (Product No. 3124), Fennel Seed (Foeniculum vulgare) (Product No. 3126), Nerves (Product No. 1287), Truman's Hoxy Tumors BeGone (Product No. 1022), Bilberry Complex (Product No. 8960), Can Free (Product No. 1099), Skin Tumors (external) (Product No. 1075), Antibiotic (Product No. 1009), Truman's Symplex Powder (Product No. 7210), and Black Salve (Product No. 6500).

6. Defendant has sole control over the formulation and labeling of the products he manufactures and distributes. He is also responsible for the content of his business's website, www.healthherbs.com. Defendant receives orders for his product over the website, as well as by telephone and mail-order, the number and address for which are supplied on the website.

**DEFENDANT'S PRODUCTS ARE DRUGS UNDER THE ACT**

7. Under the Act, a product is a drug if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B). Moreover, products (other than food) "intended to affect the structure or any function" of the human body are drugs within the meaning of 21 U.S.C. § 321(g)(1)(C).

8. The intended use of a product may be determined from any relevant source, including labeling. 21 C.F.R. § 201.128.

9. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

10. Defendant promotes his products for use as drugs on his website, www.healthherbs.com. The website qualifies as labeling within the meaning of 21 U.S.C. § 321(m) because it is "written, printed, or graphic matter . . . accompanying such article [of drug]." The phrase "accompanying such article" encompasses materials that supplement or explain a product, even if the materials do not travel with the product. Also, the website is part of an integrated distribution scheme because it contains a phone number and address from which customers can and do purchase Defendant's products.

11. Defendant's website explains Defendant's products by making numerous claims about many of his products that are within the definition of a "drug." Defendant's website is clear that his products are to be used in the diagnosis, cure, mitigation, treatment, or prevention of numerous diseases, including glaucoma, cataracts, and cancer. For example, FDA review of Defendant's website in June and July of 2011 showed that Defendant is making the following claims:

a. Eyebright Leaf (Euphrasia officinalis) (Product No. 3124): "This herb is specific for eye disorders. It has been used for weak and tired eyes, failing vision, inflammation, conjunctivitis, ulcers and eye strain. . . . Other indications: glaucoma, cataracts, sneezing, earache, hay fever, colds and measles with these symptoms. External uses: It has been used as an eyewash or compress."

b. Fennel Seed (Foeniculum vulgare) (Product No. 3126): "It is mainly used for digestive disorders. . . . It has been useful for colic, cramps, gas, excessive mucus, indigestion and abdominal distension. . . . [I]t makes an effective treatment for cystitis. . . . Has been used after chemotherapy and/or radiation treatments for cancer. Has been used to treat Irritable Bowel Syndrome (IBS). External uses: The cool tea can be used as an eyewash."

c. Nerves (Product No. 1287): "Can also help arteriosclerosis/atherosclerosis, arthritis, autoimmune diseases, birth prevention of defects, burns, cold sores . . . palsy . . . prostate problems, sinusitis, skin disorders."

d. Truman's Hoxy Tumors BeGone (Product No. 1022): "Helps dissolve tumors in the body; also helps with abscesses, blood purification, cystitis, growths/enlargements, hepatitis, lymphatics and skin eruptions."

e. Bilberry Complex (Product No. 8960): "Helpful for many diseases of the eyes. . . . Also useful for bleeding gums, varicose veins, and inhibition of platelet aggregation, possibly preventing blood clots. . . . Bilberry is widely used as a possible preventive treatment for diabetes."

f. Can Free (Product No. 1099): "This formula builds up the immune system, releases toxins and adds many anti-tumor constituents to help fight degenerative diseases that may cause cancer."

g. Skin Tumors (external) (Product No. 1075): "Use externally for skin tumors, skin cancer, infection and skin disorders."

h. Antibiotic (Product No. 1009): "Good for abscesses, acne, arthritis, auto-immune diseases, bladder, breast cancer/tumors, . . . cancer, chicken pox, cold sores, colds, colitis, diphtheria, . . . hypoglycemia, infection, . . . leucorrhea, lupus, lymphatic, meningitis (spinal meningitis), . . . mumps, nephritis, peritonitis, pleurisy, pneumonia, . . . scarlet fever, skin disorders, sore throat, spinal meningitis, stomach-tumors, tonsillitis, tuberculosis, tumors, and venereal disease."

i. Truman's Symplex Powder (Product No. 7210): "Truman's Symplex Powder is a topical medication for the treatment of Herpes simplex labialis. Gives instant relief for herpes, cold sores, ringworm, impetigo, and infection. There is no burning or side effects."

j. Black Salve (Product No. 6500): "Black Salve has a strong drawing power to promote healing. It has been used on such skin ailments as boils, abscesses, splinters, carbuncles, felons, skin infections, skin cancer, cysts and tumors."

12. Based on these claims, and many others found on Defendant's website, these products and other products manufactured, promoted, and distributed by Defendant are drugs under the Act.

**DEFENDANT DISTRIBUTES PRODUCTS THAT ARE UNAPPROVED NEW DRUGS**

13. Under the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application

("NDA") or abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval under an investigational new drug application ("IND"). 21 U.S.C. § 355(a), (b), (i), and (j).

14. A "new drug" is defined as any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). For a product to be deemed "generally recognized as safe and effective" ("GRAS/GRAE"), it must have substantial evidence of safety and effectiveness. 21 U.S.C. § 355(d). If it is an over-the-counter ("OTC") drug, the product must comply with a monograph established pursuant to an FDA regulation. 21 C.F.R. § 330.1.

15. The introduction or delivery for introduction into interstate commerce of an unapproved new drug is a violation of the Act, 21 U.S.C. § 331(d).

16. Defendant's drugs are "new drugs" as defined by 21 U.S.C. § 321(p)(1), because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

17. FDA has conducted a search of its records for NDA, ANDA, and IND submissions by Defendant. FDA has ascertained that Defendant has no approvals on file of an NDA, ANDA, or IND from FDA. Moreover, Defendant's drugs do not conform to

the OTC monograph set forth in 21 C.F.R. § 330.1. As a result, Defendant's drugs may not be distributed in interstate commerce.

**DEFENDANT'S PRODUCTS ARE MISBRANDED DRUGS**

18. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded is a violation of the Act, 21 U.S.C. § 331(a).

19. A drug is misbranded if its label fails to bear "adequate directions for use" as defined by 21 C.F.R. § 201.5(a), and it does not fall within a regulatory exemption from that requirement. 21 U.S.C. § 352(f)(1).

20. "Adequate directions for use" means "directions under which the layman can use a drug safely and for the purpose for which it is intended." 21 C.F.R. § 201.5(a) Because of the purposes for which they are intended, and the "collateral measures necessary to its use," the self-diagnosis and treatment of, among other diseases, glaucoma, cataracts, and cancer, Defendant's products are also prescription drugs. 21 U.S.C. § 353(b)(1)(A). By definition, prescription drugs cannot contain adequate directions for lay use. Id.

21. Defendants' drug products are misbranded under 21 U.S.C. § 352(f)(1) because they lack adequate and well-controlled studies to support the claims made for them, their labeling therefore necessarily fails to bear adequate directions for use, and, because they are unapproved new drugs, they are not exempt from that requirement. 21 C.F.R. §§ 201.100(c)(2), 201.115.

## DEFENDANT ENGAGES IN INTERSTATE COMMERCE

22. Defendant's products may be ordered over his website for shipment throughout the country. In July 2011, FDA purchased ten products for which Defendant's website makes drug claims. The purchases resulted in the products being shipped from Albany, Oregon to both Maryland and Washington. Such shipments constitute the introduction or delivery for introduction into interstate commerce of drugs within the meaning of 21 U.S.C. § 331(a) and (d).

## HISTORY

23. FDA conducted an inspection of Defendant's manufacturing facility in September 2004 and as a result of that inspection sent Defendant a Warning Letter dated March 17, 2005. The Warning Letter identified seven different products, including Antibiotic (Product No. 1009) and Eyebright (Product No. 3124), manufactured and distributed by Defendant that, based on their labeling, were drugs under the Act. None of these products were generally recognized as safe and effective for the indications listed on their labeling, nor were they the subject of an approved NDA, ANDA, or IND. The 2005 Warning Letter instructed Defendant that, under 21 U.S.C. § 331(d), continued distribution of these products was prohibited.

24. FDA conducted a review of Defendant's website in 2006 and despite the earlier Warning Letter, Defendant was continuing to make claims about his products that caused them to be drugs under the Act. On January 16, 2007, FDA issued a second Warning Letter to Defendant identifying twelve products, including Bilberry Complex and Nerves that, based on their labeling, were drugs under the Act. As before, none of

these products were generally recognized as safe and effective for the indications listed on their labeling, nor were they the subject of an approved NDA, ANDA, or IND. The 2007 Warning Letter once again advised Defendant that continued distribution of these products violated the Act.

25. Both the 2005 and the 2007 Warning Letters advised Defendant that continued violations could result in further regulatory action including seizure and/or injunction. Defendant made some changes to the labeling material but continues to violate the Act.

26. Defendant is promoting products to cure, mitigate, treat, prevent, and/or reduce the risk of diseases including, but not limited to, glaucoma, cataracts, and cancer. Defendant is not in compliance with the Act, and unless restrained by order of this Court, Defendant will continue to distribute unapproved new and misbranded drugs in violation of the Act, 21 U.S.C. § 331(a) and (d).

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 331(a) and (d), Defendant, and each and all of his agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done, any of the following acts:

A. Violating 21 U.S.C. § 331(d) by distributing unapproved new drugs in interstate commerce; and

B. Violating 21 U.S.C. § 331(a) by distributing misbranded drugs in interstate commerce.

II. Order Defendant, and each and all of his agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, to cease promoting and distributing any product unless and until:

A. An approved new drug application or abbreviated new drug application pursuant to 21 U.S.C. § 355(a) or (j) is in effect for the product; or

B. An investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) is in effect for the product; or

C. Defendant has removed all claims from Defendant's product labels, labeling, promotional materials, websites owned or controlled by or related to Defendant, and in any other media that cause that product to be a drug as defined by the Act; and

III. Grant Plaintiff a judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED this 18th day of November, 2011

TONY WEST
Assistant Attorney General
MAAME EWUSI-MENSAH FRIMPONG
Acting Deputy Assistant Attorney General
Civil Division
U.S. DEPARTMENT OF JUSTICE

S. AMANDA MARSHALL
United States Attorney

NEIL J. EVANS
Assistant U.S. Attorney
1000 SW Third Ave., Suite 600
Portland, OR 97204
(503) 727-1000

OF COUNSEL:

WILLIAM B. SCHULTZ
Acting General Counsel

ELIZABETH DICKINSON
Acting Associate General
Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel,
Litigation

JOHN H. FUSON
Associate Chief Counsel
United States Department of
Health and Human Services
Office of the General Counsel
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
(301) 796-85

MICHAEL S. BLUME
Director
Consumer Protection Branch

JOHN W. BURKE
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
Civil Division
P.O. Box 386
Washington, DC 20044
(202) 353-2001